

Notice of Allowability	Application No.	Applicant(s)	
	10/658,782	ARCANGEL ET AL.	
	Examiner	Art Unit	
	M. Franco Salvoza	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendments filed 05/02/06.
2. ☒ The allowed claim(s) is/are 3,6-16,19 and 22-34.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| <ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>09/23/04</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>07/24/06</u> 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
|---|---|

DETAILED ACTION

Claims 3, 6, 19 have been amended.

Claims 3, 6-16, 19, 22-32 are pending and under consideration.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Roberta Robins on July 24, 2006.

The application has been amended as follows:

Claim 3. A method of detecting hepatitis C virus (HCV) infection in a biological sample, said method comprising:

(a) providing an immunoassay solid support comprising HCV antigens bound thereto, wherein the HCV antigens consist of one or more HCV NS3/4a antigens wherein at least one of the NS3/4a antigens comprises a conformational epitope and comprises amino acids 2-686 of SEQ ID NO:2;

(b) combining a biological sample with said solid support under conditions which allow HCV antibodies, when present in the biological sample, to bind to said one or more NS3/4a antigens;

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(c) adding to the solid support from step (b) under complex-forming conditions a detectably labeled HCV multiple epitope fusion antigen (MEFA), wherein said labeled MEFA comprises at least one epitope from the HCV NS3/4a region and a consensus sequence from the E2 hypervariable region spanning amino acids 390-410 having with the sequence of SEQ ID NO:7, wherein said MEFA binds said bound HCV antibody;

(d) detecting complexes formed between said HCV antibody and said NS3/4a antigen and said MEFA, if any, as an indication of HCV infection in the biological sample.

Claim 19. A method of detecting hepatitis C virus (HCV) infection in a biological sample, said method comprising:

(a) providing an immunoassay solid support comprising HCV antigens bound thereto, wherein the HCV antigens consist of one or more multiple epitope fusion antigens (MEFAs) wherein said one or more MEFAS comprise at least one epitope from the HCV NS3/4a region and a consensus sequence from the E2 hypervariable region spanning amino acids 390-410 having with the sequence of SEQ ID NO:7;

(b) combining a biological sample with said solid support under conditions which allow HCV antibodies, when present in the biological sample, to bind to said one or more MEFAs;

(c) adding to the solid support from step (b) under complex-forming conditions a detectably labeled HCV NS3/4a antigen comprising a conformational epitope, wherein said detectably labeled NS3/4a antigen binds said bound HCV antibody, and further wherein said NS3/4a antigen comprises amino acids 2-686 of SEQ ID NO:2;

(d) detecting complexes formed between said HCV antibody and said detectably labeled

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NS3/4a antigen and said MEFA, if any, as an indication of HCV infection in the biological sample.

The following is an examiner's statement of reasons for allowance: The prior art does not disclose a NS3/4a antigen comprising amino acids 2-686 of SEQ ID NO:2 or a sequence of SEQ ID NO:7. Much of the art is closely homologous (e.g.: 99%; see BLAST search results) but no prior art has 100% alignment with amino acids 2-686 of SEQ ID NO: 2.

The restriction is withdrawn as to claims 33 and 34, which are rejoined.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


Puntoriero et al. (1998) teaches a HCV HVR1 consensus sequence that is similar to SEQ ID NO:7.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


M. Franco Salyoza
Patent Examiner
July 21, 2006



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